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VALIDATION OF PROMIS EMOTIONAL DISTRESS SHORT FORM SCALES FOR CERVICAL CANCER

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Abstract

Objectives—Cervical cancer patients are at high risk for emotional distress. In this study we evaluate the PROMIS Emotional Distress-Depression and -Anxiety Short Forms for assessing depression and anxiety in a cervical cancer population.

Methods—A 15-item questionnaire was used in a cervical cancer biobehavioral randomized clinical trial, testing psychosocial telephone counseling (PTC) against usual care (UC). It was administered to 204 patients prior to randomization, four months post-enrollment, and nine months post-enrollment, together with legacy measures of depression. The short forms were evaluated in patients participating in this study over three time points for internal consistency, convergent validity, and responsiveness to change over time.

Results—Overall, 45% and 47% of patients scored in the moderate to severe range for anxiety and depression, respectively. Internal consistency coefficients were ≥0.95 at baseline, 4 months,

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Author contributions

Justin Wilford contributed through literature review, data review and interpretation, and manuscript development.

Kathryn Osann conducted all statistical analyses.

Bradley J. Monk contributed through initial clinical trial development and results interpretation of the primary endpoints of the clinical trial.

Edward L. Nelson contributed through initial clinical trial development and results interpretation of the primary endpoints of the clinical trial.

Lari Wenzel contributed through initial clinical trial development, conceptualization of the psychometric properties required for this paper, and results interpretation.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

and 9 months for depression and anxiety. The average inter-item correlation was 0.65 and 0.73 at baseline assessment for depression and anxiety, respectively. The depression short form T-score was correlated with legacy distress scales ranging from 0.44–0.76, and the anxiety short form ranging from 0.45–0.78. The depression short form demonstrated sensitivity to change as patients randomized to the counseling intervention reported greater improvement over time in depression (p=0.014), and a nonsignificant improvement in anxiety, compared to the patients receiving usual care.

Conclusions—The PROMIS depression and anxiety short forms reliably and validly assess cervical cancer-specific emotional distress, capture salient features of distress in this population, and perform as well or better than legacy measures.

Keywords

patient-reported outcomes; cervical cancer; depression; anxiety

Introduction

Cervical cancer survivors experience quality of life (QOL) disruptions which are often severe and prolonged [1–3]. This disruption can include compromised emotional well-being [4–6]. The majority of clinical studies that assess QOL in cervical cancer patients generally report changes over time in physical, functional, or symptom-specific concerns [7–9], without specific reference to emotional well-being or distress. It is notable however, that in 2014 the American Society of Clinical Oncology (ASCO) issued guidelines reinforcing the need to care for psychological needs of cancer survivors, specifically recommending that all people who have been treated for cancer be evaluated for symptoms of depression and anxiety. This premise is contained in Quality Oncology Practice Initiative (QOPI) certification, which recognizes that a patient's emotional well-being should be assessed and documented in the chart, thereby demonstrating commitment to delivering the highest quality of cancer care.

Emotional distress may well deserve even greater attention in the context of cervical cancer care and survivorship, since distress in this population is frequently associated with advanced disease, long-term treatment sequelae, and lower socioeconomic status [6, 10, 11], and is likely to be associated with poor treatment compliance [12, 13]. PROMIS emotional distress short forms have previously been noted to reliably and validly assess depression and anxiety in several disease contexts [14–19]. Moreover, a cancer-specific PROMIS module has been created [20] which incorporates the emotional distress short forms and has shown to converge with expert clinical judgement [21], be appropriate in a variety of cancer settings [22] and several different modes of administration [23].

Results from a biobehavioral randomized trial demonstrated an improvement in emotional distress, as measured by PROMIS short forms of depression and anxiety, among cervical cancer patients randomized to a psychosocial telephone counseling (PTC) intervention, compared to those who received usual care [25]. The improvement was most evident between the baseline and four-month assessment interval, which coincided with 'active treatment.' These study results helped to reaffirm the importance of addressing emotional

distress in the cervical cancer population; second, they indicated that emotional distress is amenable to change and improvement; and third, they demonstrated that use of a psychometrically sound measure of distress, appropriate to the sociodemographic and disease characteristics of this population, can provide a robust and significant contribution to study and treatment planning. The evaluation of psychometric properties and performance of the PROMIS emotional distress short forms administered in this randomized trial [25] is the subject of the current report, and adds to the body of literature noting the importance of emotional well-being measurement among cervical cancer patients.

Materials and Methods

Study population

Our biobehavioral study sought to determine if the use of PTC could improve patient-reported outcomes, compared to usual care. Primary and secondary objectives, patient eligibility, recruitment and retention, and details of PTC administration and results were previously published [5, 25]. Survivors of cervical cancer were identified from the California Cancer Registries (Orange, Los Angeles, Imperial, and San Diego Counties). Eligibility criteria were 1) stage 1 to IVA cervical cancer (locally advanced but without disseminated metastasis), 2) completion of definitive treatment at least 2 months earlier, and 3) ability to speak and read English or Spanish. Exclusion criteria were 1) treatment with biologic response modifiers or prior immunotherapy within 4 weeks of study enrollment, 2) treatment with investigational drugs within 30 days, 3) required corticosteroids, and 4) immunosuppression. After passive physician approval for contact, eligible survivors were contacted via mail and telephone. Participants were enrolled in the trial at ≥ 9 and less than 30 months from diagnosis. All patients provided informed consent consistent with all federal, state and local requirements prior to enrolling in the study.

Patients were stratified based on language preference (English or Spanish) and randomly allocated to PTC or usual care. The PTC counseling intervention was, in general, conducted weekly for five weeks with a one-month booster session. The short-term outcome was assessed four months after study enrollment. A longer-term outcome was assessed nine months after study enrollment.

Measures

PROMIS Emotional Distress Short Forms.—The PROMIS emotional distress short forms (SF) consist of 15 items, 8 items on depression (Depression – Short Form 8a) and 7 items on anxiety (Anxiety – Short Form 7a). PROMIS measures were developed, beginning in 2004, out of a collaborative process funded by the National Institutes of Health (NIH) Roadmap for Medical Research Initiative [26]. Mental health (along with physical functioning, fatigue, pain, and social participation) was identified as a core patient-reported outcome early in the development process. Using expert review and quantitative analysis of existing data, the PROMIS steering committee identified emotional distress as a key domain of mental health, and defined its three subdomains as depression, anxiety, and anger. Depression was defined as “low levels of positive affect,” anxiety as “autonomic arousal and

experience of threat," and anger as "hostility," "cynicism," and "frustration" regarding "goal-directed behavior" [27].

Each item in the PROMIS emotional distress SF was scored from 1 to 5 points where 1=never, 2=rarely, 3=sometimes, 4=often, and 5=always. Consistent with PROMIS scoring convention, the scale score was computed using proration when more than 50% of items were answered. A high score on these PROMIS short forms connotes more emotional distress (i.e., more depression or anxiety). With a standardized normative T-score of 50 and a standard deviation of 10, T-scores <55 would translate as normal; 55–60 as mild; 60–70 as moderate, and ≥70 as severe distress [28].

Legacy Measures.—PROMIS short form scales are substantially shorter, and thus may confer an advantage over many legacy measures. The following legacy measures were included in this study to demonstrate relationships between PROMIS depression and anxiety short-form scales and legacy measures which could be related to mood.

The Functional Assessment of Cancer Therapy-Cervical (FACT-Cx) is a multidimensional, combined generic and disease-specific QOL questionnaire for cervical cancer patients. The FACT-G (general) questionnaire (version 4) is a 27-item self-report measure developed specifically for cancer patients and designed for use in a variety of settings [29]. It consists of four subscales (physical well-being (PWB), social well-being (SWB), emotional well-being EWB), functional well-being (FWB)) that can be analyzed separately or summed to produce a total QOL score. Eleven additional items represent cervical cancer-specific problems. The FACT Trial Outcome Index (FACT-TOI) is the sum of the FACT subdomains PWB, FWB and cancer-specific concerns. The Brief Symptom Inventory (BSI-18) [30] is a shortened version of the BSI, developed to assess psychological distress. Each item is rated on a 5-point Likert scale from 0 (not at all) to 4 (always). Patients are asked to respond to each item in terms of "how they have been feeling during the past 7 days." The BSI-18 includes subscales measuring depression, anxiety, and somatization, as well as an overall total score.

The Impact of Event Scale (IES) [31] is a 15-item Likert scale to measure distress related to cancer. The IES has two sub-scales: (a) intrusive thoughts and feelings, and (b) avoidance of thoughts and feelings related to the stressful situation. The 10-item Perceived Stress Scale (PSS) assesses perceptions of stress over the past month [32] [33]. Items reflect how frequently the patient experienced a specific feeling/state, and are rated on a 5-point Likert scale (0=never to 4=very often). The Medical Outcomes Survey Social Support (MOS-SS) questionnaire, a 19-item multidimensional, self-administered survey of social support was developed for the Medical Outcomes Survey for patients with chronic conditions [34]. Responses are ranked on a Likert scale from 1 (none of the time) to 5 (all of the time), and indicate how often respondents perceive the availability of a particular source of support.

Patient Reported Assessments

Surveys were mailed in advance, with follow-up phone calls as needed. Patients completed PROs prior to randomization and at the 4- and 9-month assessment intervals by rating the accuracy of statements concerning signs and symptoms for the previous 7 days in the case of

PROMIS, FACT-Cx, BSI, and IES; for the past month in the case of PSS; and in general in the case of MOS-SS. Legacy measure properties can be found in Table 1. PROMIS emotional distress short form properties can be found in Table 2.

Statistical Considerations

Reliability.—The standardized Cronbach's alpha coefficient was used to assess the internal consistency of the PROMIS short forms. Coefficients are generally regarded as acceptable if they are above 0.7, good if above 0.8, and excellent if above 0.9 [35].

Convergent Validity.—Convergent validity was examined for correlations between items using Spearman correlations due to the ordinal nature of item scores (1 to 5). Correlations between items and total raw scores were calculated after excluding the item from the total score. Agreement between the short form and other legacy measures of psychosocial distress as well as quality of life and social support, was estimated using Pearson correlation coefficients between T-score values and legacy measures.

Responsiveness to Change over Time.—The sensitivity of the short forms to change over time, including responsiveness to PTC, was examined with paired t-tests for the change in depression and anxiety scores from baseline to the 4-month assessment among the patients who completed both baseline and 4 month assessment in both PTC and control arms. It was hypothesized that emotional distress would decrease significantly for the counseled patients, compared to those receiving usual care. Effect sizes were calculated as the difference in change over time between arms divided by the standard deviation.

Results

Patient Characteristics

Between September 2008 and November 2011, 204 eligible patients were randomly allocated to receive either PTC (n=115) or usual care (UC) (n=89). The majority of patients were non-Hispanic white (51%), 41% were Hispanic, and 8% were Asian, African American or native American. Seventy-five percent (154/204, including 87 PTC and 67 UC) completed all questionnaires in English while 25% (n=50) completed questionnaires in Spanish. The mean age was 44.7 years. At diagnosis, 72% of patients were stage I, 12% stage II, 14% stage III-IVa and 2% unknown stage. Table 3 describes the sociodemographic characteristics of the study population. Psychometric results are reported based on combined study treatment arms (PTC and UC), for patients who completed the PROMIS measures at baseline for reliability and validity, with study treatment arms separately for responsiveness to change.

Assessment Completion

Completion rates for PROMIS measures were 99.5% for baseline (n=203), 82% (n=166) at the four-month assessment and 74% (n=151) at 9 months. Ninety-six percent of questionnaires (196) provided valid answers for all PROMIS items; 6 questionnaires had 1 missing item and 1 had 2 missing items. Ninety-nine percent of questionnaires provided valid answers for legacy questionnaires (i.e., FACT-Cx, BSI, IES, PSS, MOS-SS). The

primary reasons for not completing assessments was loss to follow-up (25% PTC, 6% UC) with 1% of patients providing insufficient answers on the questionnaire.

Internal Consistency

The standardized Cronbach's coefficient (Cronbach's alpha) was calculated to evaluate the internal consistency of the 8 item PROMIS short form Depression, and the 7 item PROMIS short form Anxiety. At baseline, 4-month and 9-month assessments, Cronbach's alpha coefficients were 0.95, 0.95 and 0.96 for Depression and 0.96, 0.95 and 0.95 for Anxiety, indicating excellent internal consistency.

Convergent Validity

The convergent validity of the PROMIS short forms was assessed by calculating the Spearman rank correlation coefficient between items. All correlation coefficients between PROMIS short form items and with legacy scales at baseline can be found in Tables 4–5. The average inter-item correlation at baseline was 0.65 for Depression and 0.73 for Anxiety; item-total correlations (calculated after exclusion of the item from the total) ranged from 0.74–0.89. Item correlations with other scales including the FACT-Cx, PWB, SWB, EWB, FWB, Additional Concerns subscale, FACT-TOI , and MOS-SS were negative and ranged from −0.39 to −0.62 while correlations with the BSI, IES and PSS were positive and ranged from 0.44 to 0.76. For Anxiety, item correlations with legacy measures ranged from −0.29 to −0.59 for the FACT measures and MOS-SS and from 0.33 to 0.68 for the BSI, IES and PSS. Within the range of moderate to strong correlations, the strongest correlations between PROMIS T-scores and legacy scores were with the BSI subdomain standard scores for Depression and Anxiety, the BSI-GSI standard score and the PSS (0.78, 0.70 and 0.64 for the Depression T-score and 0.65, 0.61 and 0.60 for the Anxiety T-score).

Responsiveness to Change over Time

Sensitivity or responsiveness to change over time includes an ability to detect clinically relevant differences that may exist after patients received treatments, and between patients receiving different treatments. In the absence of disease recurrence, it was hypothesized that quality of life would improve over time as patients were further removed from cancer treatment, potentially independent of PTC vs UC. Therefore, it was also expected that patients' depression and anxiety would also improve over time. Further, we hypothesized that those receiving PTC would improve at a more significant rate than those randomized to usual care. Thus, usual care patients were considered a reference group for evaluating the short forms' sensitivity to treatment differences. While baseline scores were similar for PTC and UC, at the four-month assessment interval, PTC patients reported significantly greater improvement in depression compared to UC patients (mean change=−3.1 in PTC vs. −0.6 in UC adjusted for age and baseline value, p=0.014) [25]. This improvement approached a clinically meaningful increase (considered to be 3–5 points [36]). PTC patients also showed greater improvement in anxiety, but the difference did not reach statistical significance (mean change = −3.0 in PTC vs. −0.9 in UC adjusted for age and baseline level, p=0.068).

Changes over time in the BSI-18 depression and anxiety subscales, legacy measures that are also standardized to mean 50 and SD 10, were similar in PTC and UC arms. Effect sizes

were comparable between the PROMIS, BSI and PS measures (0.25, 0.21 and 0.24 respectively for depression/stress change at 4 months; 0.13, 0.17 and 0.14 respectively for depression/stress at 9 months). Effect sizes for change in anxiety on PROMIS and BSI measures were 0.22 and 0.21 at 4 months, and 0.12 and 0.19 for anxiety at 9 months. Effect sizes for PROMIS, BSI and PS measures were larger than for other legacy measures including the FACT-Cx, FACT-TOI, FACT-EWB and IES (range: 0.02–0.14). English and Spanish speakers experienced similar decreases in depression and anxiety over time in both arms with no statistically significant differences ($p>0.5$).

Change over time was also assessed by comparing the number and proportion of patients retained reporting clinically meaningful depression (T-score≥55) across follow-up intervals (Table 6). Among those who remained in the study, the number with depression T-scores>55 decreased by 14% for PTC and by 12% for UC at the 9-month follow-up. Numbers with clinically meaningful anxiety also decreased over time in both arms but to a smaller degree. Notably, the baseline scores of moderate to severe depression from the total sample (N=203) were 48/114 (42%) of PTC and 44/89 (49%) of UC, and those scoring in the moderate to severe anxiety range were 52/114 (46%) of PTC and 44/89 (49%) of UC. Correlations for change in PROMIS short form scores with change in scores for select legacy measures are presented in Table 6.

Discussion

We administered the PROMIS depression (8 items) and anxiety (7 items) short forms to cervical cancer patients participating in a biobehavioral clinical trial. We found that the PROMIS depression and anxiety short forms reliably and validly assess emotional distress in cervical cancer patients, are responsive to change, and perform as well or better than legacy measures. This conclusion supports the re-emphasis and growing body of oncology literature acknowledging the importance of screening for emotional distress in cancer patient populations, and the need to do so in a manner which can ultimately be integrated into the health care system with little burden [24].

Our results, specific to cervical cancer, provide additional PROMIS validation for its use in specific cancer patient populations. For example, in a recent large, US population-based sample of patients with recently diagnosed cancer, T-score reference values were identified which could help facilitate interpretation of the PROMIS domain scores in research studies or in clinical applications [36]. As previously noted, many of these factors, including emotional distress, which contribute to overall poor QoL are amenable to supportive care interventions and should be evaluated at the time of primary treatment [5]. While the prevalence of depression among cancer patients varies considerably in the literature, these estimates range from 15 – 40% [37, 38]. It is therefore noteworthy and alarming that at study entry our population of cervical cancer survivors report a significant rate of moderate to severe depression and anxiety, ranging from 42–49%. It is well-recognized that even moderate levels of distress may affect recruitment and retention into clinical trials [39, 40], as was the case in our trial [25], or completion of recommended treatment regimens [5, 12, 13].

This study contributes new evidence demonstrating validity and reliability of PROMIS depression and anxiety short forms in cervical cancer survivors, demonstrates comparability of effect sizes to several emotional distress legacy measures, and presents opportunities to administer these in static or computer-adaptive testing forms to diverse populations, further enhancing feasibility and decreasing burden. A self-assessment tool enabling patients to report their emotional distress can provide additional information concerning the disease, short and long-term treatment effects, and importantly adjustments in care that can improve patient-reported outcomes.

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Highlights:

- PROMIS depression and anxiety short forms reliably and validly assess cervical cancer-specific emotional distress.
- PROMIS depression and anxiety short forms perform as well or better than legacy measures among cervical cancer survivors.

The depression short form demonstrated sensitivity to change over time.

Table 1.

Patient-reported emotional distress measures examined

Instrument	Number of Items	Subdomains
Functional Assessment of Cancer Therapy - Cervical Cancer (FACT-Cx)	42	Physical well-being; Social/family well-being; Emotional well-being; Functional well-being; Additional concerns
Brief Symptom Inventory - Global Severity Index (BSI-GSI)	53	Somatization; Obsessive-compulsive; Interpersonal sensitivity; Depression; Anxiety; Hostility; Phobic anxiety; Paranoid ideation; Psychoticism
Impact of Event Scale (IES)	22	Intrusion; Avoidance; Hyperarousal
Perceived Stress Scale (PSS)	10	No subdomains
Medical Outcomes Study - Social Support (MOS-SS)	18	Emotional/informational; Tangible; Affectionate; Positive social interaction
PROMIS Emotional Distress	15	Anxiety; Depression

Table 2.

PROMIS emotional distress short form properties at baseline

PROMIS item identifier	Floor	Ceiling	Mean	SD	Item text
	Emotional Distress - Anxiety				
EDANX01	1	5	2.196	1.240	In the past 7 days I felt fearful…
EDANX05	1	5	2.396	1.286	In the past 7 days I felt anxious…
EDANX30	1	5	2.660	1.238	In the past 7 days I felt worried…
EDANX40	1	5	1.920	1.133	In the past 7 days I found it hard to focus on anything other than my anxiety…
EDANX46	1	5	2.197	1.219	In the past 7 days I felt nervous…
EDANX53	1	5	2.187	1.158	In the past 7 days I felt uneasy…
EDANX54	1	5	2.557	1.223	In the past 7 days I felt tense…
	Emotional Distress - Depression				
EDDEP04	1	5	1.975	1.123	In the past 7 days I felt worthless…
EDDEP05	1	5	1.803	1.077	In the past 7 days I felt that I had nothing to look forward to…
EDDEP06	1	5	1.876	1.100	In the past 7 days I felt helpless…
EDDEP17	1	5	2.552	1.135	In the past 7 days I felt sad…
EDDEP22	1	5	1.945	1.128	In the past 7 days I felt like a failure…
EDDEP29	1	5	2.591	1.245	In the past 7 days I felt depressed…
EDDEP36	1	5	2.424	1.201	In the past 7 days I felt unhappy…
EDDEP41	1	5	1.926	1.111	In the past 7 days I felt hopeless…

Table 3:

Descriptive characteristics and baseline legacy measures for study sample (n=204)

	N	Mean	SD
Age at study	204	44.71	9.58
Diagnosis to T1 (mo)	204	19.33	5.41
ED Depression T-Score	203	53.31	9.77
ED Anxiety T-Score	203	53.85	11.40
FACT-CX	203	124.73	24.28
FACT-TOI	200	86.85	17.36
FACT-PWB	201	22.71	5.50
FACT-SWB	203	19.94	5.96
FACT-EWB	204	17.73	4.67
FACT-FWB	204	20.23	6.40
FACT-Additional Concerns	203	44.01	8.26
BSI-GSI Standard Score	204	12.50	11.54
BSI Depression Standard Score	204	54.65	11.46
BSI Anxiety Standard Score	204	46.55	9.93
IES Total	200	18.21	17.90
PSS Total	189	17.86	7.53
SS Total	203	3.84	0.92
		Frequency	**Percent**
Race/Ethnicity	Caucasian/Non-Hispanic	105	51.5
	African-American	4	2.0
	Hispanic	83	40.7
	Asian/Pacific Islander	11	5.4
	Native American	1	0.5
Marital Status	Single	31	15.3
	Married	129	63.6
	Sep/Wid/Div	43	21.1
Income	<$15,000	51	29.3
Refused/unknown=29	$15,000-$35,000	32	18.4
	$35,000-$55,000	25	14.4
	>$55,000	66	37.9
Education	< High School	43	21.3
Unknown=2	High School graduate	40	19.8
	Some college	56	27.7
	College graduate	33	16.3
	Graduate/professional	30	14.9
Stage	I	147	73.1
	II	28	13.9

	N	Mean	SD
	III-IVA	26	12.9
	Unknown	3	
Treatment	Surgery only	100	49.0
	Radiation only	15	7.4
	Chemo +/− Radiation	89	43.6

Table 4:

Correlations between items and with legacy scales for PROMIS short-form Depression measure

	EDDEP04	EDDEP05	EDDEP06	EDDEP17	EDDEP22	EDDEP29	EDDEP36	EDDEP41	EDDEP Total[a]	EDDEP T-Score
EDDEP04	1	0.741	0.696	0.657	0.741	0.696	0.655	0.676	0.839	
EDDEP05		1	0.716	0.625	0.663	0.559	0.569	0.636	0.739	
EDDEP06			1	0.647	0.604	0.555	0.616	0.683	0.751	
EDDEP17				1	0.555	0.787	0.638	0.604	0.767	
EDDEP22					1	0.634	0.593	0.655	0.758	
EDDEP29						1	0.691	0.695	0.782	
EDDEP36							1	0.74	0.755	
EDDEP41								1	0.786	
ED_DEP Total									1	
FACT-CX	−0.59	−0.49	−0.57	−0.55	−0.53	−0.59	−0.50	−0.54	−0.66	−0.62
FACT-TOI	−0.57	−0.46	−0.54	−0.52	−0.51	−0.57	−0.48	−0.52	−0.63	−0.58
FACT-PWB	−0.45	−0.35	−0.44	−0.43	−0.39	−0.47	−0.38	−0.44	−0.51	−0.47
FACT-SWB	−0.33	−0.35	−0.35	−0.36	−0.29	−0.37	−0.31	−0.33	−0.41	−0.39
FACT-EWB	−0.56	−0.43	−0.49	−0.47	−0.47	−0.50	−0.45	−0.49	−0.58	−0.55
FACT-FWB	−0.51	−0.43	−0.48	−0.46	−0.46	−0.52	−0.45	−0.46	−0.57	−0.53
FACT-AdConcerns	−0.49	−0.39	−0.46	−0.44	−0.45	−0.48	−0.40	−0.44	−0.53	−0.49
BSI-GSI Std Score	0.68	0.55	0.59	0.62	0.60	0.64	0.58	0.55	0.72	0.70
BSI Dep Std Score	0.73	0.63	0.63	0.65	0.66	0.67	0.64	0.61	0.78	0.76
IES Total	0.35	0.38	0.37	0.34	0.38	0.37	0.33	0.45	0.45	0.44
PSS Total	0.57	0.47	0.58	0.50	0.57	0.53	0.59	0.56	0.66	0.64
SS Total	−0.32	−0.32	−0.34	−0.31	−0.29	−0.35	−0.39	−0.37	−0.40	−0.39

Item-item correlations are Spearman correlations (n=199)

[a]Correlations between items and EDDEP Total exclude the specified item from the total score (n=199)

Correlations with legacy measures are Pearson correlations (n=180)

Table 5:

Correlations between items and with legacy scales for PROMIS short-form Anxiety measure

	EDANX01	EDANX05	EDANX30	EDANX40	EDANX46	EDANX53	EDANX54	EDANX Total	EDANX T-Score
EDANX01	1	0.68	0.77	0.65	0.75	0.73	0.61	0.78	
EDANX05		1	0.72	0.74	0.77	0.77	0.70	0.82	
EDANX30			1	0.70	0.73	0.72	0.69	0.82	
EDANX40				1	0.79	0.74	0.70	0.81	
EDANX46					1	0.89	0.72	0.89	
EDANX53						1	0.74	0.88	
EDANX54							1	0.79	
EDANX Total								1	
FACT-CX	−0.59	−0.49	−0.57	−0.55	−0.53	−0.59	−0.50	−0.54	−0.66
FACT-TOI	−0.57	−0.46	−0.54	−0.52	−0.51	−0.57	−0.48	−0.52	−0.63
FACT-PWB	−0.45	−0.35	−0.44	−0.43	−0.39	−0.47	−0.38	−0.44	−0.51
FACT-SWB	−0.33	−0.35	−0.35	−0.36	−0.29	−0.37	−0.31	−0.33	−0.41
FACT-EWB	−0.56	−0.43	−0.49	−0.47	−0.47	−0.50	−0.45	−0.49	−0.58
FACT-FWB	−0.51	−0.43	−0.48	−0.46	−0.46	−0.52	−0.45	−0.46	−0.57
FACT-AdConcerns	−0.49	−0.39	−0.46	−0.44	−0.45	−0.48	−0.40	−0.44	−0.53
BSI-GSI Std Score	0.68	0.55	0.59	0.62	0.60	0.64	0.58	0.55	0.72
BSI Dep Std Score	0.73	0.63	0.63	0.65	0.66	0.67	0.64	0.61	0.78
IES Total	0.35	0.38	0.37	0.34	0.38	0.37	0.33	0.45	0.45
PSS Total	0.57	0.47	0.58	0.50	0.57	0.53	0.59	0.56	0.66
SS Total	−0.32	−0.32	−0.34	−0.31	−0.29	−0.35	−0.39	−0.37	−0.40

Item-item correlations are Spearman correlations (n=199)

Correlations between items and EDDEP Total exclude the specified item from the total score (n=199)

Correlations with legacy measures are Pearson correlations (n=179)

Table 6:

PROMIS Depression and Anxiety over time and Pearson Correlations for change in PROMIS Depression and Anxiety with change in legacy measures

	Depression T-Score *			Anxiety T-Score *		
	T1	**T2**	**T3**	**T1**	**T2**	**T3**
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
PTC	53.7 (9.9)	48.6 (10.1)	48.6 (9.4)	53.8 (11.8)	49.4 (10.0)	48.4 (10.7)
UC	52.8 (9.6)	51.8 (8.9)	51.1 (10.2)	53.9 (11.0)	52.1 (10.1)	51.3 (10.3)
	Prevalence of Clinical Depression + (T-Score>55)			**Prevalence of Clinical Anxiety + (T-Score>55)**		
	T1	**T2**	**T3**	**T1**	**T2**	**T3**
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
PTC	25 (33)[a]	21 (28)	14 (18)	28 (37)[b]	21 (28)	24 (32)
UC	37 (51)[a]	30 (41)	28 (38)	36 (49)[b]	31 (42)	28 (38)
Pearson Correlations with		**Change in Depression T-Score**			**Change in Anxiety T-Score**	
Change in Legacy Measures		**T2−T1**	**T3−T1**		**T2−T1**	**T3−T1**
FACT-Cx	T2−T1	−0.35		T2−T1	−0.22	
	T3−T1		−0.54	T3−T1		−0.27
FACT-TOI	T2−T1	−0.25		T2−T1	−0.13	
	T3−T1		−0.51	T3−T1		−0.22
FACT-EWB	T2−T1	−0.39		T2−T1	−0.37	
	T3−T1		−0.48	T3−T1		−0.40
BSI Depression Standard Score	T2−T1	0.41		T2−T1		
	T3−T1		0.58	T3−T1		
BSI Anxiety Standard Score	T2−T1			T2−T1	0.41	
	T3−T1			T3−T1		0.37

*Unadjusted

+Includes only those completing assessment at all time points (n=149).

[a]Among all patients including dropouts (n=203), depression T-score was ≥55 for 48/114 (42%) for PTC and 44/89 (49%) for UC at baseline (T1).

[b]Among all patients including dropouts (n=203), anxiety T-score was ≥55 for 52/114 (46%) for PTC and 44/89 (49%) for UC at baseline (T1).